Case 1:16-cv-01090-NGG-TAM Document 82 Filed 07/07/23 Page 1 of 7 PageID #: 659

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July 7, 2023

VIA ECF W/ COURTESY COPY VIA FIRST CLASS MAIL

Hon. Nicholas G. Garaufis United States District Judge Eastern District of New York 225 Cadman Plaza East Brooklyn, NY 11201

Re: *United States ex rel. YNKDY-2 v. Shiel Medical Laboratory, et al.* Civil Action No. 16-CV-1090

Dear Judge Garaufis:

We are co-counsel for Jack Basch ("Mr. Basch"), a named defendant in the above-captioned *qui tam* matter brought by corporate relator YNKDY-2 ("Relator") that was unsealed on June 14, 2022 (ECF 28) following the federal and state governments' unanimous decisions to decline intervention (ECF 24-27). On May 2, 2023, Magistrate Judge Merkl ordered defendants to file their "anticipated pre-motion conference letters" by today's date. In accordance with Your Honor's Individual Rule V(A)(2)(a), we write to respectfully request that the Court schedule a premotion conference to discuss Mr. Basch's contemplated motion to dismiss Relator's Third Amended Complaint (the "TAC") pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(6), 10(a), and 9(b). In accordance with Your Honor's Individual Rule V(A)(3), we also respectfully request that the Court extend Mr. Basch's time to respond to the TAC to a date to be determined at the conference.

This matter was filed under seal in March 2016 pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA") and state-based FCA analogues and other laws alleging, *inter alia*, that Defendants knowingly submitted claims for reimbursement for laboratory tests that were not reasonable or necessary or that were furnished through improper referrals and kickbacks. Relator is a single-purpose California corporation whose only function is to assert the claims of an unnamed individual (the "Anonymous Individual"). Relator claims that the Anonymous Individual "held a senior position with [named Defendant] Shiel" and has "direct and personal knowledge of the matters alleged," TAC ¶ 10, yet hides the identity of that sole person whose knowledge allegedly supports all the TAC's allegations.

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¹ Magistrate Judge Merkl's May 2, 2023, Order provided: "Defendants shall file their anticipated premotion conference letters within 30 days of the date Plaintiffs file proof of service of the Amended Complaint on the non-appearing Defendants, or by 7/24/2023, whichever is earlier." Relator filed these proofs of service on June 7, 2023 (ECF 79 & 80), making this letter due today.

The TAC cobbles together 45 pages of generalized allegations about supposedly inappropriate clinical laboratory testing that Relator seeks to parlay, through unsupported inferences, into a windfall recovery. The TAC is, however, deficient in multiple ways—a conclusion that the United States, the State of New York, the State of New Jersey, and the State of Connecticut all appear to have reached given their declinations of intervention. (ECF 24-27.) This matter, which Relator now seeks to pursue on its own, should be dismissed in its entirety, with prejudice.

I. <u>Under Fed. R. Civ. P. 10(a) and 12(b)(1), Relator is Not A Proper Party</u>

This case may not proceed based on the claims made by Relator, a corporate shell, without naming the Anonymous Individual, the *only* person who allegedly has "direct and personal knowledge" of the TAC's claims. (TAC \P 10.). This case squarely presents an issue that courts have not yet addressed head on: whether an individual on whose sole purported knowledge an FCA complaint is based may hide his identity from FCA *qui tam* defendants behind a shell corporation formed for the sole purpose of serving as relator in an FCA action. The answer is "no."

First, Mr. Basch should not be expected to respond to fraud allegations from an unidentified source. Relator is a California corporation incorporated a month before the original Complaint was filed with the only purpose of bringing this suit.³ The TAC conflates the

United States ex rel. CKD Project, LLC v. Fresenius, 2022 WL 17818587 (2d Cir. Dec. 20, 2022), involved an anonymous relator, but the court was not presented with the question, nor required to decide, whether the FCA allows an individual relator to hide anonymously behind a shell corporation. The court addressed only the defendants' argument that relator's claims should be dismissed in accordance with the FCA "public disclosure bar," under which a court may dismiss a case if substantially the same allegations as those made by a relator were previously disclosed unless the relator is the "original source of the information" (the pre-2010 standard), or "materially adds" to public disclosures (the post 2010 standard). Id., at *2 (citing 31 U.S.C. § 3730(e)(4)(A)). The public disclosure bar is not an issue here, so far as Mr. Basch is currently aware, but what is relevant is the court's analysis that:

CKD Project does not possess direct knowledge of the information on which that allegations are based. *CKD Project is an entity formed solely for this litigation*. It acquired its information from a third party whom the amended complaint describes as "an inside participant in one of the fraudulent joint venture transactions." ... *The inside participant might possess direct knowledge, but CKD Project does not*.

Id., at *3. This language only serves to support Mr. Basch's argument, below, that the TAC should be dismissed under Fed. R. Civ. P. 9(b) because Relator, which does not have direct knowledge of the facts underlying the TAC's claims, has not pled those claims with sufficient particularity and, in fact *cannot* do so without identifying the Anonymous Relator. See also n. 8, below.

³ See https://bizfileonline.sos.ca.gov/search/business. YNKDY 2 was first filed as a California corporation on February 2, 2016. The original Complaint was filed on March 4, 2023.

Anonymous Individual with Relator's undefined "Principal/Agent," TAC ¶ 10,⁴ Relator's registered "Agent" is Mark A. Kleiman, Relator's attorney, who specializes in bringing FCA *qui tam* cases (his e-mail is mkleiman@quitam.org, TAC ¶ 171), and who incorporated Relator solely to bring this suit.⁵ Knowing the identity of Relator's attorney and the corporation he formed is of no help to Mr. Basch since the TAC completely hides the source of Relator's allegations. Mr. Basch is thus deprived of basic tools to meaningfully analyze and respond to the TAC. *See United States ex rel. Graves v. Internet Corporation for Assigned Names and Numbers, Inc.*, 398 F. Supp. 3d 1307, 1313 (N.D. Ga. 2019) ("the False Claims Act contemplates the added difficulty of the Government declining to intervene by adding a greater financial incentive for relators who continue to prosecute *but does not provide for the ability to do so anonymously*") (emphasis added); *United States v. Aurora Diagnostics, Inc.*, 2017 WL 8781118, at *3 (S.D. Fla., Aug. 30, 2017) (same).

Second, allowing the Anonymous Individual to hide behind a corporate shell violates the fundamental presumption of openness in judicial proceedings. Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 597-99 (1978) ("It is clear that the courts of this country recognize a general right to inspect and copy ... judicial records and documents."). In FCA actions, this presumption "is 'especially strong [because] the filings involve matters of particular concern to the public, such as allegations of fraud against the government." United States ex rel. Jack Permison v. Superlative Techs., 492 F. Supp. 2d 561, 564 (E.D. Va. 2007) (citing Under Seal v. Under Seal, 27 F.3d 564 (Table), 1994 WL 283977, at *2 (4th Cir. June 27, 1994)).

A recent increase in the use of shell corporate entities as "relators" formed exclusively to bring FCA suits threatens to undermine these principles. *Cf. United States v. UCB, Inc.*, 970 F.3d 835, 852 (7th Cir. 2020) (describing with disapproval a corporate relator as an "investment vehicl[e] for financial speculators"). Relator is an improper plaintiff, a speculative vehicle to seek a financial windfall while concealing the Anonymous Individual's identity.

Third, the TAC also violates Fed. R. Civ. P. 10(a), which codifies the rule of open disclosure, providing that "the title of the complaint must name all the parties." The Second Circuit has held: "This requirement, though seemingly pedestrian, serves the vital purpose of facilitating public scrutiny of judicial proceedings and therefore cannot be set aside lightly. Certainly, '[i]dentifying the parties to the proceeding is an important dimension of publicness. The people

While the TAC also alleges, much later, that the Anonymous Individual "is *one of the principals* [plural] who formed the corporate entity which is the Relator in this action," TAC ¶ 167 (emphasis added), this is at odds with the allegation, under "Jurisdiction, Venue, Parties," that a *single* principal "on *his* own initiative" allegedly "contacted federal law enforcement[.]" TAC ¶ 10 (emphasis added). The description of Relator, singular, under "Parties," governs analysis of the TAC.

Kleiman is Relator's registered agent. See https://bizfileonline.sos.ca.gov/search/business. At least one other Kleiman YKNDY entity, YKNDY 3, Inc., also brought a *qui tam* action, *YNKDY 3 v. Dermone*, *LLC et al.*, D.N.J. Case No 2:16-cv-01967, filed April 8, 2016, which was dismissed on October 3, 2017 after the government declined to intervene.

have a right to know who is using their courts." *Sealed Plaintiff v. Sealed Defendant*, 537 F.3d 185, 188-89 (2d Cir. 2008) (citation omitted).

Courts have carved out only a "limited number of exceptions to the general requirement of disclosure," where an individual plaintiff's "interest in anonymity [is] balanced against both the public interest in disclosure and any prejudice to the defendant," by considering, *inter alia*, whether the matter is "highly sensitive and [of a] personal nature," "whether identification poses a risk of retaliatory physical or mental harm," *and* "whether the defendant is prejudiced by allowing the plaintiff to press his claims anonymously[.]" *Sealed Plaintiff*, 537 F.3d at 189-90 (internal citations omitted). The use of a corporate shell to hide the Anonymous Individual's identity makes an end run around the requirement that a plaintiff establish facts demonstrating why nondisclosure is necessary, while certainly prejudicing defendants.

In fact, courts that directly address the issue routinely reject individual FCA relators' attempts at anonymity. See United States ex Rel Doe v. Horizon Therapeutics PLC, 2021 WL 3500911, at *1-2 (S.D.N.Y. Aug. 8, 2021) (refusing to extend FCA seal despite relator's claim that "[d]efendants and others could potentially decipher Relator's identity based on the allegations of the pleadings" and so allegedly harm his professional reputation); *United States ex rel. Wenzel v.* Pfizer, Inc., 881 F. Supp. 2d 217, 222 (D. Mass. 2012) (refusing to seal qui tam complaint despite relator's claim that he would face blacklisting by healthcare industry); United States v. UCB, Inc., 2017 WL 838198, at *2 (S.D.N.Y. Mar. 3, 2017) ("Courts generally do not find that the risk of employer retaliation outweighs the presumption of public access to documents filed in FCA actions.") (collecting cases); Doe v. Care One, LLC, 2021 WL 4428579, at *2 (D.N.J. Sept. 7, 2021) (unpub. dec.) (ordering relator's identity revealed after relator dismissed action with prejudice, because "[w]ithout knowing who Relator is, Defendants would be unable to assert a res judicata defense against a subsequent suit brought by Relator"). Cf. United States v. Amador, 2022 WL 594548, at *1 (D. Nev. Feb. 25, 2022 "[t]here is nothing in the FCA suggesting that the initial seal was imposed to protect the identity of the relator or that gui tam complaints in which the Government decides not to intervene should be permanently sealed."") (citation omitted; collecting cases).

Fourth, Relator does not have standing, requiring dismissal under Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction. While some corporate relators may have been deemed proper plaintiffs, no case has squarely held that an entity formed specifically to conceal the identity of the only person with purported knowledge of the facts alleged in a complaint, may, to keep hiding that identity, serve as the sole relator in a qui tam action. See, e.g., Federal Recovery Services, Inc. v. U.S., 72 F.3d 447, 448 (5th Cir. 1995) (president and shareholders of relator corporation identified by name); Lab'y Corp. of America Holdings, 2011 WL 3718625, at *1 (S.D.N.Y. Aug. 29, 2022 (individual source of allegations identified by name). Cf. United States ex rel. Anti-Discrimination Center of Metro New York, Inc. v. Westchester County, New York, 495 F. Supp. 2d 375, 377-78 & n.3 (S.D.N.Y. 2007) (before relator filed suit, defendant's representative met with relator's executive director to discuss facts underlying relator's claims); A1 Procurment, LLC v. Hendry Corp., 2013 WL 12065531, at *1-2 (S.D. Fla. Jun. 26, 2013) (relator and defendant had history, pre-FCA complaint, of bidding disputes regarding federal contracts). The Relator here, which is nothing more than an empty shell formed and used to hide

the Anonymous Individual's identity, lacks standing, and the TAC should accordingly be dismissed, with prejudice, for lack of subject matter jurisdiction.⁶

II. Relator's Claims Fail under Fed. R. Civ. P. 12(b)(6) and 9(b)

For at least the following reasons, Relator's claims are also subject to dismissal pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b).

First, as to all of the allegations in the TAC, Relator has failed to plead with the requisite particularity mandated by Fed. R. Civ. P. 9(b), which applies in cases brought pursuant to the FCA and its state-based analogues. See United States v. Lab'y Corp. of Am. Holdings, No. 107 Civ. 05696, 2015 WL 7292774, at *3 (S.D.N.Y. Nov. 17, 2015) (citations omitted). Rather, Relator asserts conclusorily that all of the "Defendants" engaged in conduct that they collectively "knew" was inappropriate, but does not make sufficient specific allegations regarding Mr. Basch (nor other Defendants). Relator's entire 181-paragraph TAC mentions Mr. Basch in only seven paragraphs (¶ 2, 12, 15, 85, 105, 106, 136), three of which are merely descriptive and non-substantive (¶ 2, 12, 15). Nowhere does Relator allege with any particularity, much less that required by Fed. R. Civ. P. 9(b), that Mr. Basch personally made or caused to be made any specific false claim, nor the "where, when, or how" of such conduct, nor that Mr. Basch did so intentionally or knowingly—all of which are required to state a claim under the FCA. See, e.g., U.S. ex rel. Kester v. Novartis Pharms. Corp., 23 F. Supp. 3d 242, 255 (S.D.N.Y. 2014). Relator's claims are ripe for dismissal for lack of particularity.

Second, Relator's claims that Defendants submitted claims for tests "that were not reasonable and necessary" and that it "made, used, and caused to be made or used" false statements to get false claims paid "by the United States" should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6) for failure to state a claim. To begin with, Relator's conclusions about the laws and

Relator's retaliation claims should also be dismissed on jurisdictional grounds. These claims are asserted not by Relator, but rather by Relator's anonymous principal, who is not actually a party to this action; Relator itself, which is not alleged to have ever been (nor, as a corporation, could it ever have been) an employee of any of the Defendants, much less one that allegedly engaged in protected activity, does not have standing to bring retaliation claims under the FCA or NJ CEPA. See 31 U.S.C. § 3730(h) (only an individual "employee, contractor, or agent" of an FCA defendant may seek relief); N.J.S.A. 34:19–1, et seq.

Although individual relators in *Doe 1 v. EviCore Healthcare MSI, LLC*, 2023 WL 2249577 (2d Cir. Feb. 28, 2023), were listed anonymously in the complaint, anonymity was not an issue the court addressed. See n.2, above. Instead, the court affirmed dismissal because the complaint violated Fed. R. Civ. P. 9(b), when it was allegedly "based on Relators' 'personal knowledge' and 'their own personal investigation," *id.*, at *1, but "failed to identify even a single instance of a medical procedure, involving any particular patient on a specific date, that was fraudulent or unnecessary but that was nevertheless approved by eviCore," *id.*, at *2. The same lack of specificity as to a particular laboratory test allegedly improperly billed in connection with a particular patient on a specific date dooms the TAC here.

regulations governing clinical laboratory testing are, variously, irrelevant, incomplete, misleading, and just flat-out wrong, so even if Relator's factual allegations did pass muster under applicable pleading standards, Relator would still not be entitled to relief on these claims, and this Court need not accept Relator's faulty legal conclusions as true even on a motion to dismiss. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions"). In the reverse, as demonstrated above, Relator's claims regarding lack of medical necessity and false certification are devoid of sufficient supporting factual allegations and are subject to dismissal even if Relator's legal theories were correct (which they are not). These claims should be dismissed.

Third, Relator's FCA claims based on purported violations of the federal Antikickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"), fail to allege that (or how) Mr. Basch knowingly and willfully violated the AKS, as is required to state FCA claims based on AKS violations. United States ex rel. Hart v. McKesson Corp., No. 15-CV-0903 (RA), 2022 WL 1423476, at *12 (S.D.N.Y. May 5, 2022). To satisfy the AKS's "heightened intent requirement," a relator must allege that the defendant "knew the conduct was unlawful and proceeded with the business practice regardless." Hart, 2022 WL 1423476 at *15. Here, the TAC contains only conclusory allegations regarding the collective "Defendants" alleged scienter. See, e.g., TAC ¶¶ 119-20. These allegations are insufficient to state AKS claims under the FCA and its state-based analogues. See Hart, 2022 WL 1423476, at *15.

Fourth, Relator's FCA claims premised on alleged violations of the federal Physician Self-Referral Law, 42 U.S.C. § 1395nn (the "Stark Law"), similarly fail to allege the necessary elements and details of such violations. *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019). The TAC alleges no details whatsoever regarding the purported Stark Law violations that underlie its alleged FCA claims, much less about how Mr. Basch was involved in those purported violations, and asserts only, in wholly conclusory fashion, that "Defendant knowingly compensated physicians and skilled nursing facilities in exchange for referrals, in violation of the Stark Law." TAC ¶ 120. The Stark Law claims should be dismissed.

Fifth, Relator's claim that Defendants failed to return retained overpayments in violation of the so-called "reverse" false claims provisions of the FCA—which "boil down to [Defendants] allegedly receiving payment on false claims and thus retaining Government funds to which they were not entitled"—is not an adequate basis on which to allege a reverse false claim. United States ex rel. Gelbman v. City of New York, 2018 WL 4761575, at *8 (S.D.N.Y. Sept. 30, 2018). Indeed, as the Second Circuit recently held in United States ex rel. Foreman v. AECOM, et al., 19 F.4th 85 (2d Cir. 2021), reverse false claims cannot "turn on the same conduct underlying a traditional false claim," and "reverse false claims" that "mirror" a relator's direct "false claims under § 3729(a)(1)(A)" should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6). Id. at 119-20.

Case 1:16-cv-01090-NGG-TAM Document 82 Filed 07/07/23 Page 7 of 7 PageID #: 665

Hon. Nicholas G. Garaufis
Re: United States ex rel. YNKDY-2 v. Shiel Medical Laboratory, et al. Civil Action No. 16-CV-1090
July 7, 2023
Page 7

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For at least the foregoing reasons, 8 as well the reasons set out in Fresenius Medical Care Holdings, Inc.'s and Spectra Holdco, LLC's joint June 1, 2023 letter requesting a pre motion conference (ECF 72), and today's letter to the Court from counsel for Defendants Shiel Medical Laboratory and BIM Medical Inc., Mr. Basch intends to file a motion to dismiss the claims against him, with prejudice, and respectfully requests that the Court: (1) schedule a Pre-Motion Conference to discuss that anticipated motion, and; (2) extend Mr. Basch's time to answer, move, or otherwise respond to the TAC, to a date to be determined at the conference.

We thank the Court for its time and attention to this matter.

Respectfully submitted,

Claude Millman

On behalf of all counsel for Jack Basch

cc:

All Counsel of Record (via ECF)
Rachel G. Balaban (via U.S. Mail), Counsel for the United States
Diana Elkind (via U.S. Mail), Counsel for State of New York
Charisse M. Penalver (via U.S. Mail), Counsel for State of New Jersey

The TAC should also be dismissed in light of "substantial arguments that the *qui tam* device is inconsistent with Article II [of the U.S. Constitution] and that private relators may not represent the interests of the United States in litigation." *United States, ex rel. Polansky v. Executive Health Resources, Inc.*, __U.S. __, 143 S. Ct. 1720, 1737 (June 16, 2023) (Kavanaugh, J., concurring; Barrett, J., joining) (quoting Thomas, J., dissenting, *id.* at 1741). In his very brief concurrence, Justice Kavanaugh agreed with Justice Thomas's language in dissent, above, and concluded: "In my view, the Court should consider the competing arguments on the Article II issue in an appropriate case." *Id.* at 1737 (Kavanaugh, J., concurring). Justice Barrett joined in this conclusion. This is such an appropriate case. The matter has not proceeded beyond the filing of three amended complaints and pre-motion conference requests by the defendants, and Mr. Basch intends to elaborate on the "complex [legal] questions" raised by Justice Thomas, *id.* at 1742; *see generally id.* at 1740-42, and demonstrate that Article II does not, in fact, permit *qui tam* cases such as this.